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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,824

09/22/2003

Michael Charles Cheney

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7590

06/27/2007

UNILEVER INTELLECTUAL PROPERTY GROUP
700 SYLVAN AVENUE,
BLDG C2 SOUTH
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

06/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/667,824		CHENEY ET AL.	
	Examiner		Art Unit	
	Lakshmi S. Channavajjala		1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment, remarks and terminal disclaimer all dated 4-5-07 is acknowledge.

Claims 9-20 have been added in the amendment dated 4-5-07. Claims 1-20 are pending.

The terminal disclaimer filed on 4-5-07 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 10/767,679 has been reviewed and is accepted. The terminal disclaimer has been recorded. Accordingly, the double patenting rejection has been withdrawn.

Response to Arguments

Applicant's arguments filed 4-5-07 have been fully considered but they are not persuasive.

It is to be noted that a translated copy of the JP 07206626 has been attached to this document.

The following rejection of record has been maintained:

1. Claims 1 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 07206626 (JP) in view of US 4,867,967 ('967) OR JP in view of US 7,067,556 ('556).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

JP teaches that dicarboxylic acid salts such as sodium salt of malonic acid possess good antimicrobial and antiseptic properties and can be used in skin cosmetic compositions. While JP fails to teach ammonium salt of malonic acid, JP teaches sodium salt and in the absence of any unexpected advantage of a specific salt form over the other, a skilled artisan would have expected the same antimicrobial and antiseptic activity with the any salt of malonic acid. JP does not teach the claimed method.

The invention of '556 and '967 are directed to topical antimicrobial compositions. Both '556 and '967 teach that antimicrobial compositions containing effective amount of an antimicrobial agent are effective in treating pseudofolliculitis or in -grown hairs (col. 5, L 40-61 of '56, col. 6, L 18-37. of '556; abstract, col. 3, L 9-22, L 55-67 col. 4, L 41-44). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ the malonate comprising composition of JP for treating in grown hairs and pseudofolliculitis because '967. as well as '556 suggest that a method to treat pseudofolliculitis or in-grown hairs should have superior disinfecting, antimicrobial properties so as to reduce the secondary infections that cause pseudofolliculitis and malonic acid salts are effective antimicrobial agents (JP). A skilled artisan would have expected to achieve a treatment for in-grown hairs and pseudofolliculitis with the malonic acid salts of JP because the claimed compounds also possess antimicrobial, antiseptic and disinfectant properties and cause no skin irritation. Further, '967 teach that the composition can be used in the form of a crème, lotion, lotion, salve etc (col. 4, L 40-44), after or before shaving (examples and claim of '967)

and also using electric razors as an alternative to mechanical razors (col. 2). Therefore, the timing of application of the instant composition and the combination of the instant composition and an electric razor are within the scope of a skilled artisan.

New claims 9 and 12-20 are rejected under this section for reasons of record.

2. Claim 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 07206626 (JP) in view of US 4,867,967 ('967) OR JP in view of US 7,067,556 ('556) as applied to claims 1 and 3-8 above, and further in view of US 5,641,495 to Jokura ('495).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

JP does not teach the claimed ratio of neutralization of malonic acid.

'495 teach a skin cosmetic composition comprising ceramides, a dicarboxylic acid and a salt of dicarboxylic acid, for moisturizing the keratinous layer of the skin. In particular, '495 teach malonic acid and its salts, including the claimed ammonium salts (col. 2, L 30-50). Thus a skilled artisan would have employed an ammonium salt of malonic acid in place of the sodium salt of malonic acid and still expect to achieve the same effect because '495 teach that the various salts of malonic acid are equivalent. With respect to the claimed neutralization, while '495 fails to teach the claimed ratio, '495 suggests adding a salt form of the acid (assuming complete neutralization) or adding acid followed by addition of an alkali to the composition to thereby form the aimed salt by neutralization within the system (col. 3, L 45-50). Thus, in the second

option, a completely neutralized salt is not formed and the neutralization process occurs within the system, suggesting a complete neutralization is not an absolute requirement. In this regard, applicants have not shown any unexpected advantage with respect to the claimed full and partial neutralization. Therefore, absent such criticality, choosing a completely neutralized salt or partially neutralized salt or a mixture thereof in the composition of JP would have been within the scope of skilled artisan because according to '495, both forms of salt are effective in providing a moisturizing effect on the skin.

New claims 10 and 11 have been rejected under this section for the reasons above.

RESPONSE: Applicants argue that ethanol is known antiseptic and that the abstract do not clarify if the dicarboxylic acids provide antiseptic effect. A translated document of JP references shows that in fact the dicarboxylic acids were tested for their germicidal action and were shown to be effective (paragraphs 0015 and 0017). As opposed to applicants' statement that JP might have taught the dicarboxylic acids to ameliorate the antiseptic activity of ethanol, JP teaches preparing a solution of the above acids in ethanol (i.e., ethanol not used as an antiseptic and instead as a solvent). In this regard, it is noted that instant claims while reciting a method of controlling in-grown hair do not recite any specific activity of the dicarboxylic acids. Whereas, JP clearly states that the dicarboxylic acid salts preserve the composition from decay (0024). Applicants mention on page 10 (last lines) that a skilled art seeking to solve pseudofolliculitis would not select dicarboxylic acids if they were not strongly antimicrobial. Applicants argue that neither Butcher nor Bhagawat teach dicarboxylic acids and that there is no motivation to

employ the teachings of these references. However, JP teaches the dicarboxylic acid compositions for cosmetic use and recognizes the antiseptic property of these compounds/. Butcher and Bhagawat teach the use of antimicrobial agents in several skin compositions including for the treatment of pseudofolliculitis. Accordingly, a skilled artisan would have recognized that the compounds of JP could be successfully used as antimicrobial agents for skin applications including pseudofolliculitis treatment.

With respect to the argument regarding the "consisting essentially of" in claim 9 to exclude ethanol, it is to be noted the above phrase is treated as 'comprising' absent showing that ethanol of the prior art affects the basic and novel features of the instant composition. Further, the comprising language of claim 1 does not exclude ethanol of JP.

Applicants argue that Jokura does not remedy the deficiencies of JP because Jokura lacks the teaching that the compounds are antimicrobial. However, as revealed by the translation, JP teaches antimicrobial properties of instant compounds.

In response to the amendment, the rejection of claims 1-8 under 35 USC 112, first paragraph as not being enabled has been withdrawn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

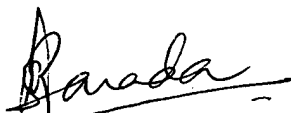
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
June 11, 2007

A handwritten signature in black ink, appearing to read 'Lakshmi S. Channavaajjala', with a horizontal line drawn underneath the signature.

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER